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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/11/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/991,028

Applicant(s)
Smith-templeton

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: :1615

DETAILED ACTION

Claims included in the prosecution are 1-19. The added claims 15-17 by amendment dated 11-20-01 have been renumbered as 17-19 according to rule 126.

Double Patenting

- 1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).**

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: :1615

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,413,544. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic 'liposome' and 'sandwich liposome' encompass the specific 'sandwich liposome' recited in claims 1 and 2 of said patent. Instant process of preparation which is the same as the patented process (claim 3), but drawn to generic 'biologically active agent' encompasses the DNA in the patented claim.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claim 1-4 and 6-7 rejected under 35 U.S.C. 102(a) as being anticipated by Sternberg (J. Of Liposome Research, 6 (3), pp., 515-533, 1996).

Art Unit: :1615

Sternberg discloses instant liposomes; the liposomes contain DOTAP and cholesterol (note the figure on page 522).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 5. Claims 1-14 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by WO93/25673 of record.**

WO discloses liposomes made of DOTAP, cholesterol derivative and DNA (note the abstract, Examples, example 2 in particular). The liposomes can be targeted (page 29).

Since WO discloses liposomes containing the same components and prepared by sonication, the burden is upon applicant to show that the prior art liposomes are different from instant liposomes.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

- 6. Claims 1-14 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Debs (5,827,703).**

Debs discloses liposomes containing DOTAP, Cholesterol derivative and DNA (note the abstract and Example 2 on columns 19-20. Since Debs discloses liposomes containing the same components and prepared by sonication, the burden is upon applicant to show that the prior art liposomes are different from instant liposomes.

Art Unit: :1615

7. Claim 1-14 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Felgner (5,580,859).

Felgner discloses instant liposomes; liposomes contain DOTAP, cholesterol and nucleic acids (note col. 26, line 51 and example 6). Since Felgner discloses liposomes containing the same components and prepared by sonication, the burden is upon applicant to show that the prior art liposomes are different from instant liposomes.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-14 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sternberg or Felgner cited above.

As pointed out above, Sternberg teaches sandwich liposomes prepared with cationic amphiphiles such as lipofectin and DOTAP. Although Sternberg teaches the combination of the cationic lipid lipofectin and a cholesterol in the preparation of liposomes, Sternberg does not provide a specific example showing the combination of instant lipid (DOTAP) with the cholesterol derivative. However, it is deemed obvious to one of ordinary skill in the art to use the combination with the expectation of obtaining similar liposomes with the

Art Unit: :1615

guidance provided by Sternberg. Similarly, Felgner does not specifically teach the inclusion of cholesterol derivatives in the example provided. The inclusion of cholesterol would have been obvious to one of ordinary skill in the art based on the guidance provided by Felgner.

11. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sternberg or Felgner or Debs or WO cited above, further in view of Wasan (Journ. Pharmaceutical Sciences, 85 (4), pp., 427-433, 1996) and Kitaguchi (5,206,027).

The primary references do not teach the sizing of the liposomes formed by extrusion through filters. The use of such a technique however would have been obvious to one of ordinary skill in the art since the references of Wasan and Kitaguchi both show that this technique is routinely practiced for liposomal sizing (note Experimental section in Wasan; examples in Kitaguchi).

The references cited are all of record in the parent application.

Art Unit: :1615

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Art Unit: :1615

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

July 8, 2003